AO 120 (Rev. 3/04)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Trenton on the following ☑ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
08-4718	9/19/2008	Trenton

PLAINTIFF	DEFENDANT
Sepracor Inc. and University of Massachusetts	Pharmaceutical Associates, Inc.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	7,214,683		SEE ATTACHED COMPLAINT
2	7,214,684		
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
WILLIAM T. WALSH		9/22/2008

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

LOCAL CIVIL RULE 11.2 & 40.1 CERTIFICATION

I hereby certify that the matters captioned: (1) *Schering Corporation v. Zydus Pharmaceuticals, USA, Inc., et al.*, Civil Action No. 06-4715 (MLC) (D.N.J.); (2) *Schering Corporation v. Caraco Pharmaceutical Laboratories Ltd., et al.*, Civil Action No. 06-14386 (E.D. Mich.); and (3) *Schering Corporation v. GeoPharma Inc., et al.*, Civil Action No. 06-1843 (M.D. Fla.), which have been consolidated before the Honorable Mary L. Cooper under the caption, *In Re: Desloratadine Patent Litigation*, MDL No. 1851 (MLC) (D.N.J.), are related patent infringement cases because all of the patents asserted in the current matter and the previously identified matter are associated with Clarinex® products.

I also certify that the matters captioned: (1) *Sepracor Inc., et al. v. Sun Pharmaceutical Industries Ltd.*, Civil Action No. 07-4213; (2) *Sepracor Inc., et al. v. Orchid Chemicals & Pharmaceuticals Ltd., et al.*, Civil Action No. 07-4623; (3) *Sepracor Inc., et al. v. Glenmark Pharmaceuticals, Ltd., et al.*, Civil Action No. 07-3385; (4) *Sepracor Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 07-5001; (5) *Sepracor Inc., et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civil Action No. 07-5017; (6) *Sepracor Inc., et al. v. Perrigo Research and Development Company, et al.*, Civil Action No. 07-5136; (7) *Sepracor Inc., et al. v. Lupin Limited, et al.*, Civil Action No. 07-5265; (8) *Sepracor Inc., et al. v. Anchen Pharmaceuticals, Inc.*, Civil Action No. 07-5737; (9) *Sepracor Inc., et al. v. Sandoz, Inc.*, Civil Action No. 07-6107 (*Sandoz I*); (10) *Sepracor Inc., et al. v. Sandoz, Inc.*, Civil Action No. 08-1584 (*Sandoz II*); and (11) *Sepracor Inc., et al. v. GeoPharma, Inc., et al.*, Civil Action No. 08-945, which were consolidated by Chief Judge Brown on March 26, 2008 (*Sandoz II* was consolidated on April 3, 2008) as *Sepracor Inc., et al. v. Sun Pharmaceutical Industries Ltd., et*

al., Civil Action No. 07-4213 (MLC) (D.N.J.), are related actions because they involve the same plaintiffs and two of the same patents as the matter in controversy.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 19, 2008

Respectfully submitted,

s/ Charles M. Lizza

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEPRACOR INC. and UNIVERSITY OF MASSACHUSETTS,	**Civil Action No.:**
Plaintiffs,	
v.	**COMPLAINT FOR PATENT INFRINGEMENT**
PHARMACEUTICAL ASSOCIATES, INC.,	
Defendant.	**(Filed Electronically)**

Plaintiffs Sepracor Inc. ("Sepracor") and University of Massachusetts ("UMass"), by their attorneys, for their Complaint against Defendant Pharmaceutical Associates, Inc. ("PAI"), hereby allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, arising from PAI's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of the patented Clarinex® Oral Syrup 0.5 mg/mL drug product prior to the expiration of United States Patent No. 7,214,683 ("the

'683 patent") and United States Patent No. 7,214,684 ("the '684 patent"), which are owned by Sepracor and UMass.

The Parties

2. Plaintiff Sepracor is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

3. Plaintiff UMass is a public institution of higher education of the Commonwealth of Massachusetts, having a place of business at 55 Lake Avenue North, Worcester, Massachusetts 01655.

4. Upon information and belief, PAI is a South Carolina corporation, having a place of business at 201 Delaware Street, Greenville, South Carolina 29605. Upon information and belief, PAI manufactures numerous products, which are marketed for sale and use throughout the Untied States, including in this judicial district.

5. Upon information and belief, PAI is in the business of formulating, manufacturing, and packaging generic products, which are copies of products invented and developed by innovator pharmaceutical companies.

6. Upon information and belief, PAI assembled and caused to be filed with the FDA, pursuant to 21 U.S.C. § 355(j), ANDA No. 90-616 concerning a generic version of an oral syrup containing 0.5 milligrams of the active ingredient desloratadine per milliliter of solution, which is sold as a commercial product under the trade name Clarinex® ("PAI's Proposed Product").

7. Upon information and belief, if ANDA No. 90-616 is approved, PAI will manufacture, distribute and/or sell PAI's Proposed Product in the United States.

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over PAI by virtue of, *inter alia*, the above and below stated facts.

10. Upon information and belief, PAI manufactures, markets, and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, PAI has conducted and continues to conduct business, directly, and/or through its subsidiaries, agents and/or alter-egos in this judicial district, and this judicial district is a likely destination of PAI's Proposed Product.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents In Suit and the Clarinex® Drug Product

12. On May 8, 2007, the '683 patent, entitled "Compositions of Descarboethoxyloratadine," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '683 patent. A copy of the '683 patent is attached hereto as Exhibit A.

13. On May 8, 2007, the '684 patent, entitled "Methods for the Treatment of Allergic Rhinitis," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '684 patent. A copy of the '684 patent is attached hereto as Exhibit B.

14. The '683 and '684 patents are identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" in association with the

oral syrup containing 0.5 mg/mL of the active ingredient desloratadine, which is sold as a commercial product under the trade name Clarinex®, and those patents cover an approved use of commercial Clarinex®.

Acts Giving Rise to this Action

15. Plaintiffs received a letter from PAI, dated August 19, 2008 ("the Notification Letter"), notifying them that PAI had filed with the FDA an ANDA (No. 90-616) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale or sale of oral syrup containing 0.5 mg/mL of the active ingredient desloratadine, a generic version of the Clarinex® product.

16. Upon information and belief, PAI intends to engage and will engage in the commercial manufacture, importation, use, offer for sale or sale of PAI's Proposed Product promptly upon receiving FDA approval to do so.

17. The Notification Letter states that ANDA 90-616 contains a "Paragraph IV Certification" that, in PAI's opinion, the '683 and '684 patents are invalid.

18. The Notification Letter does not allege that the '683 and '684 patents are unenforceable or that the commercial manufacture, use, sale or offer for sale of PAI's Proposed Product will not infringe claims of the '683 or the '684 patent.

19. Upon information and belief, ANDA 90-616 contains information showing that PAI's Proposed Product (a) is bioequivalent to a patented Clarinex® 0.5 mg/mL syrup product; (b) has the same active ingredient as the patented Clarinex® 0.5 mg/mL syrup product; (c) has the same route of administration and strength as the patented Clarinex® 0.5 mg/mL syrup

product; and (d) has the same, or substantially the same, proposed labeling, and the same indication and usage as the patented Clarinex® 0.5 mg/mL syrup product.

Count I – Infringement of the '683 Patent by PAI

20. Plaintiffs repeat and reallege the allegations of paragraphs 1-19 as though fully set forth herein.

21. PAI's submission of its ANDA and its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of PAI's Proposed Product, prior to the expiration of the '683 patent, constitutes infringement of one or more of the claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

22. Unless enjoined by this Court, upon FDA approval of ANDA No. 90-616, PAI will infringe the '683 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling PAI's Proposed Product in the United States.

23. PAI had notice of the '683 patent prior to undertaking its acts of infringement. PAI's certification to the FDA that the '683 patent is invalid lacked a good faith basis. PAI's filing of its ANDA constitutes a wholly unjustified infringement of the '683 patent, and makes this action exceptional under 35 U.S.C. § 285.

24. Plaintiffs will be substantially harmed if PAI's infringement of the '683 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Count II – Infringement of the '684 Patent by PAI

25. Plaintiffs repeat and reallege the allegations of paragraphs 1-24 as though fully set forth herein.

26. PAI's submission of its ANDA and its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or

sale of PAI's Proposed Product, prior to the expiration of the '684 patent, constitutes infringement of one or more of the claims of the '684 patent under 35 U.S.C. § 271(e)(2)(A).

27. Unless enjoined by this Court, upon FDA approval of ANDA No. 90-616, PAI will infringe the '684 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling PAI's Proposed Product in the United States.

28. PAI had notice of the '684 patent prior to undertaking its acts of infringement. PAI's certification to the FDA that the '684 patent is invalid lacked a good faith basis. PAI's filing of its ANDA constitutes a wholly unjustified infringement of the '684 patent, and makes this action exceptional under 35 U.S.C. § 285.

29. Plaintiffs will be substantially harmed if PAI's infringement of the '684 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Prayer for Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment declaring that PAI has infringed one or more claims of the '683 patent;

B. A Judgment declaring that PAI has infringed one or more claims of the '684 patent;

C. An Order that the effective date of any FDA approval of PAI's ANDA No. 90-616 be no earlier than the date on which the '683 patent expires, including any regulatory or patent term extension;

D. An Order that the effective date of any FDA approval of PAI's ANDA No. 90-616 be no earlier than the date on which the '684 patent expires, including any regulatory or patent term extension;

E. Preliminary and permanent injunctions enjoining PAI and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from making, using, importing, offering to sell, or selling PAI's Proposed Product until after the expiration of the '683 patent, including any regulatory or patent term extension;

F. Preliminary and permanent injunctions enjoining PAI and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from making, using, importing, offering to sell, or selling PAI's Proposed Product until after the expiration of the '684 patent, including any regulatory or patent term extension;

G. A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of PAI's Proposed Product will directly infringe or induce and/or contribute to infringement of the '683 patent;

H. A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of PAI's Proposed Product will directly infringe or induce and/or contribute to infringement of the '684 patent;

I. If PAI engages in the commercial manufacture, use, importation into the United States, offer to sell, or sale of PAI's Proposed Product prior to the expiration of the '683 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed based on the willfulness of the infringement, together with interest;

J. If PAI engages in the commercial manufacture, use, importation into the United States, offer to sell, or sale of PAI's Proposed Product prior to the expiration of the '684 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to

treble the amount found or assessed based on the willfulness of the infringement, together with interest;

K. Attorneys fees in this action based on willful infringement pursuant to 35 U.S.C. § 284 and/or as an exceptional case pursuant to 35 U.S.C. §§ 271 and 285;

L. Costs and expenses in this action; and

M. Such further and other relief as this Court may deem just and proper.

Dated: September 19, 2008

Respectfully submitted,

s/ Charles M. Lizza

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